

## REMARKS

### Claims

Claims 54–56, 60–63, 68–70, 73, 74 and 77–81 are currently under examination with claims 1–53, 55, 57, 58, 64–67, 71, 72, 75 and 76 cancelled without prejudice or disclaimer. Claim 82 is added by the paper.

### Claim amendments

New claim 82 recites claim 60 in independent form. Claim 83 is supported by the disclosure contained in, for example, page 2, ¶1 of the originally-filed specification and the references cited therein.

It is respectfully submitted that the claim amendments do not add new matter.

### Rejection under 35 U.S.C. §112, ¶1 (Written Description)

In the paragraphs bridging pages 2 and 3, the Examiner alleges that absent a description of a structure, recitation of an enzymatic function does not provide adequate written description of the claimed molecules. As such, the instant claims are rejected under §112, ¶1 for allegedly failing to provide adequate written description. Applicants disagree with these contentions.

The disclosure contained in the present specification, for example, page 2, ¶1, explicitly teaches that the genes in *S. cerevisiae* (yeast) were known in field of microbiology prior to the filing date of the instant application. The specification cites several scientific publications, for example, Basson et al. (1988), Fegueur et al. (1991), Yu et al. (1996), Jandrositz et al. (1991), which describe the molecular cloning and/or characterization of these genes. Copies of these references are enclosed herewith for the Examiner's review and submitted in an IDS attached hereto.

In the paragraph bridging pages 3 and 4 of the Office Action, the PTO alleges that "No structures, other than specific species of genes, are described" in the specification. Applicants respectfully disagree with this contention. The nucleic acid sequences of the genes recited herein were known and conventionally appreciated in the

art before the filing date of the present application. For example, the skilled worker could easily refer to the aforementioned articles, which are recited in Applicants' own specification, for a disclosure of structural and/or functional aspects of the genes recited in the claims. Based on this information, a skilled artisan can readily determine both the nature (i.e., mutant or wild-type) as well as the structure (i.e., amino acid sequence) of the proteins encoded by the genes. Reference to a particular sequence is not necessary at all. A cursory review of the aforementioned disclosures is all that is needed.

As for the nucleotide sequence of t-HMG, ERG9, ERG1 and SAT1, ADH1 genes and/or the promoter sequences associated therewith, it is now well-settled that a specification need not disclose, and preferably omits, what is well known to those skilled in the art when an application is filed (for example, with respect to the sequence of B7-H1 molecules and/or antibodies thereto). See, e.g., *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987). See, also, MPEP §2164.05(a). Indeed, the Federal Circuit found that an application, which failed to disclose the amino acid sequence of a claimed protein, was not deficient in the written description requirement, despite the fact that the undisclosed sequence was an essential part of the protein's description. *Capon v. Eshbar v. Dudas*, (Fed. Cir. 2005) 418 F.3d 1349, 76 U.S.P.Q.2d 1078. In any event, Applicants' own specification, further in view of the disclosure contained in references cited therein, provides more than adequate guidance regarding the structure of the genes, including methods of making and using the claimed genetic constructs.

Therefore, given specification's express disclosure of more than a representative number of species (for example, yeast species), further in view of the art knowledge of steroid biosynthetic pathway in yeast and humans, the skilled worker is fully in possession of written description of genes and the promoter sequences thereto.

Applicants further submit that the standards set forth in Regents of the University

*of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) has been erroneously applied since all that is required under *Lilly* is that the specification describe the molecule by “whatever characteristics sufficiently distinguish it.” To a skilled worker, the recitation of the name of the genes provides a description of the structure (i.e., polynucleotide sequences, polypeptides encoded thereby) as well as a functions of the gene products. As such, the present claims fully comply with the statutory requirements under §112, ¶1. The subject matter of the claim need not be described *in haec verba*. See, MPEP §2163.02.

Withdrawal of the rejection is respectfully requested.

New claims 82-83 are directed to method(s) wherein the microorganisms employed are yeast. Recitation of yeast gene sequences is not to be construed as acquiescence to this or any other rejection. Applicants reserve the right to reintroduce claims to cancelled subject matter during prosecution.

In view of the above-mentioned arguments and amendments, it is respectfully submitted that the claims in the application are in condition for allowance. However, if the Examiner has any questions or comments, he is cordially invited to telephone the undersigned at the number below.

The Commissioner is hereby authorized to charge any fees associated with this response to Deposit Account No. 13-3402.

Respectfully submitted,

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